

# Notice of Allowability

## Application No.

10/084,575

## Examiner

Christopher R. Tate

## Applicant(s)

NAIR ET AL.

## Art Unit

1654

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Jan 4, 2004.
2. ☒ The allowed claim(s) is/are 23,65 and 67-79.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Christopher R. Tate  
Primary Examiner  
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The response with amendments filed January 2, 2004 has been received and entered.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lynn Schwenning on March 30, 2004.

IN THE CLAIMS:

Claims 12-22 (Cancelled)

Claim 23 (Amended) A method of alleviating or reducing pain in a mammal that comprises administering an effective amount of an anthocyanin extract extracted from ~~an anthocyanin-containing plant~~ an elderberry plant to a mammal that is experiencing pain, wherein the extract comprises a mixture of anthocyanins that include cyanidin-3-glucoside, cyanidin-3,5-diglucoside, cyanidin-3-sambubioside, and cyanidin-3-sambubioside-5-glucoside, whereby the mixture of the anthocyanins ~~and which~~ comprises at least about 90% of the total extract, and wherein the extract is substantially free of anthocyanidins and the extract provides greater cyclooxygenase 2 (COX-2) inhibitory activity than cyclooxygenase 1 (COX-1) inhibitory activity.

Claims 25-27 (Cancelled)

Claims 57-64 (Cancelled)

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Claim 65 (Amended) The method of Claim ~~63~~ 23 wherein the ~~symptom of~~ pain is due to a condition selected from the group consisting of arthritis, dysmenorrhea, headache, joint pain, muscular pain, osteoarthritis, and combinations thereof.

Claim 66 (Cancelled)

Claim 67 (Amended) The method of Claim ~~66~~ 23 wherein the ~~anthocyanin-containing plant further includes~~ mammal is further administered an anthocyanin extract extracted from a tart cherry plant and a bilberry plant.

Claim 68 (New) The method of Claim 23 wherein the mammal is further administered an anthocyanin extract extracted from a tart cherry plant.

Claim 69 (New) The method of Claim 23 wherein the mammal is further administered an anthocyanin extract extracted from a bilberry plant.

Claim 70 (New) The method of Claim 68 wherein the tart cherry plant is a variety selected from Balaton, Montmorency and mixtures thereof.

Claim 71 (New) The method of claim 23 wherein the pain is an acute pain.

Claim 72 (New) The method of claim 23 wherein the pain is a chronic pain.

Claim 73 (New) The method of claim 23 wherein the extract does not produce significant erosions in the gastric lining.

Claim 74 (New) The method of claim 23 wherein the extract does not exhibit a significant propensity to induce gastric or intestinal ulceration.

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Claim 75 (New) The method of claim 23 wherein the extract is provided in a unit dosage form and wherein each dosage provides at about 20 to 50 mg of anthocyanins.

Claim 76 (New) The method of claim 23 wherein the extract is provided in a unit dosage form and wherein each dosage provides at least about 25 mg of anthocyanins.

Claim 77 ( New) The method of Claim 23 wherein the anthocyanin extract is provided in a unit dosage form and each dosage provides about 70 mg of anthocyanins.

Claim 78 (New) The method of claim 23 wherein the mammal is a human, the dosage form is an oral dosage form, and the extract is provided by oral ingestion.

Claim 79 (New) The method of claim 78 wherein after oral ingestion, the extract does not produce significant erosions in gastric lining.

### ***Reasons for Allowance***

Although the prior art teaches elderberry extract preparations for treating pain (see previous Office action), based upon the instantly disclosed method of preparing the elderberry extract (e.g., via concentrating the elderberry flavonoid solution through an ultrafiltration membrane followed by reverse osmosis, without using undersirable chemicals) - whereby the preparation method provides for an elderberry extract having the instantly claimed features/properties, the cited prior art references would not reasonably nor obviously read upon the instantly claimed method of treating a mammal in pain via administering thereto an effective amount of such an elderberry extract having the recited features/properties.

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*Drawings*

With respect to the original drawings submitted February 27, 2002, Figures 2-8 are accepted by the Examiner. However, the informal drawing representing Figure 1 should be replaced by a formal drawing which conforms to US Patent guidelines.

Claims 23, 65, and 67-79 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Brenda Brumback, can be reached at (571) 272-0961.



Christopher R. Tate  
Primary Examiner, Group 1654